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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

IN RE RIGEL PHARMACEUTICALS, INC. SECURITIES LITIGATION.

This Document Relates To: All Actions

Master File No. CV 09-0546 JSW

CLASS ACTION

RIGEL AND INDIVIDUAL DEFENDANTS' REPLY IN SUPPORT OF MOTION TO DISMISS CONSOLIDATED AMENDED COMPLAINT

Date: April 9, 2010
Time: 9:00 a.m.
Courtroom: 11, 19th floor
Judge: Hon. Jeffrey S. White

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I. INTRODUCTION

The nature of the claims asserted in Plaintiff's Consolidated Amended Complaint ("CAC") is, by now, familiar to this Court. It is also now clear, based on the arguments in the Opposition to Defendant's Motion to Dismiss ("Opp."), that those allegations fail to adequately allege claims under the relevant pleading standards.

Even at the highest levels of abstraction, the claims belie common sense. Plaintiff's core theory of the alleged fraud is that the Company and its officers concealed material information about the results of the Phase IIa study in order to mislead investors about the regulatory risk faced by R788, to enhance the prospects of a partnership that would allow the commencement of a Phase III study, and ultimately, as with all frauds, to enrich themselves. That theory is fraught with internal inconsistencies and simply cannot be reconciled with the facts subject to judicial notice. Plaintiff simply ignores the fact that the Defendants disclosed the *most serious* adverse events from the clinical trial at the beginning of the class period. Defendants then *voluntarily* disclosed the more detailed results, the results that Plaintiff alleges it tried so hard to conceal, ten months later at a medical conference and in a medical journal. Plaintiff does not allege that they were under any compulsion to do so—they were not—and the fact that they did is completely inconsistent with Plaintiff's theory.

This voluntary disclosure also came *before* any of the Defendants sold a single share of Rigel stock; all of them continued to hold their shares beyond the end of the class period. The voluntary disclosure of the detailed trial results also came *before* the Company secured a corporate partnership for the continued development of R788. The conduct of the Defendants, even as alleged in the CAC, simply is inconsistent with Plaintiff's core theory.

The CAC fares no better moving from abstract theory to the detailed allegations. No matter what statistical arguments and criticisms of Rigel's study design that Plaintiff attempts to advance as "well-pleaded facts," Plaintiff remains unable to demonstrate that Rigel's December 2007 statements were materially misleading when made; that any Defendant believed, much less knew, that any of these statements was false; or that any Defendant sold a single share of stock between December 2007 and October 2008. Further, Plaintiff's allegations that Defendants were

motivated to advance the Company's business interests and were compensated for their work, yet did not personally benefit from stock sales at artificially inflated prices, are simply inadequate to create a strong inference of scienter. Indeed, an inference that Defendants acted in good faith, without an intent to deceive, is far more cogent and compelling.

For all of these reasons, the CAC should be dismissed with prejudice.

II. PLAINTIFF HAS NOT ALLEGED SPECIFIC FACTS GIVING RISE TO A STRONG INFERENCE OF SCIENTER

It is well settled that a complaint will survive a motion to dismiss only "if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 324 (2007). Further, to establish a strong inference of scienter in an omissions case, "the plaintiff must plead 'a highly unreasonable omission, involving not merely simple, or even inexcusable negligence, but an extreme departure from the standards of ordinary care, and which presents a danger of misleading buyers or sellers that is either known to the defendant or is so obvious that the actor must have been aware of it.'" *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 991 (9th Cir. 2009) (quoting *In re Silicon Graphics Inc. Sec. Litig.*, 183 F.3d 970, 976 (9th Cir. 1999). Plaintiff has failed to satisfy these requirements.

A. Plaintiff's Theories Regarding Defendants' Motives are Undercut By Its Own Allegations and Facts Subject to Judicial Notice

Plaintiff claims that during a "critical time when Rigel was looking for a partner to back R788," Defendants concealed "disappointing efficacy results" and "adverse toxicity results" because they "knew" that disclosure "would make it more difficult, if not impossible, to raise funds." (Opp. at 24:1-2, 22:7-9.) This theory simply cannot be squared with Plaintiff's own allegations and the undisputed facts.

In 2007, the Company disclosed the most serious side effects that patients in the study experienced. Then, in the fall of 2008, the Company *voluntarily* disclosed additional detail—detail that Plaintiff alleges constituted the corrective disclosure—at a medical conference and in a medical journal when the alleged motive to entice a partner and inflate the Company's stock

value would have been no less compelling. (*See* Freeman Dec. Ex. I (10/27/08 trans.); Ex. M (November 2008 Article) at 3315.)

Indeed, Plaintiff's contention that the alleged corrective disclosures in October 2008 thwarted Rigel's prospects to partner, thereby explaining the motive to commit fraud in December 2007, makes absolutely no sense. (*See e.g.*, Opp. 21:3-9.) The Company *voluntarily* disclosed the full range of adverse events and the country interaction data in the fall of 2008, prior to having secured a partner to fund the Phase III trial. (¶¶ 132-141.) It was not trying to hide anything. If the Defendants had been trying to cover up problems with R788, they would never have made these disclosures before concluding a partnership agreement. Moreover, the fact that Rigel entered into a partnership with AstraZeneca worth at least $100 million *after* the detailed trial results were announced (Freeman Dec. Ex. S.) shows that the supposedly devastating information contained in the October 2008 disclosure was not in fact devastating at all.

Finally, Rigel's desire to find a partner and raise capital was no secret. As disclosed in its 2007 10-K, a "key element" of Rigel's "scientific and business strategy" is to "establish strategic collaborations with pharmaceutical and biotechnology companies to develop and market our product candidates." (Freeman Dec. Ex. G (12/31/07 10-K) at 2.) Thus, Rigel's February 2008 financing was never designed to make anyone personally wealthy; and in fact it did not, since no insiders sold. It was simply required to finance the Company until it could begin to derive revenues from partnership agreements. Rather, the goal was always to establish a collaboration with a third-party to develop and market R788. (¶ 132.) Had Defendants actually been acting with scienter, one would expect that they would have continued to conceal the allegedly material information and proceed to additional trials. They certainly would not have disclosed their own fraud. Plaintiff ignores this critical fact.

B. Plaintiff's Generic Motive and Opportunity Allegations Are Equally Meritless

Plaintiff has failed to make any allegations that suggest that Defendants' conduct was an "extreme departure from standards of ordinary care" or that they consciously or recklessly decided to conceal the additional patient data in an effort to mislead investors. Plaintiff fails to allege the existence of a single document, a single internal report or a single confidential witness

supporting the idea that any Defendant believed a difference in response rates among patients in different countries, mild side effects, a minor dose-dependent effect on blood pressure, or a single reading of elevated blood pressure should have been disclosed. *See, e.g., In re Silicon Graphics*, 183 F.3d at 985 (general allegations of negative internal reports and an alleged "conspiracy of silence" among defendants insufficient to allege strong inference of scienter). This should come as no surprise, as no reasonable investor would consider such data material; and its nondisclosure was no "extreme departure from the standards of ordinary care." *Zucco*, 552 F.3d at 991.

Instead, Plaintiff points to potential financial benefits to Defendants, in the form of bonuses, salary increases and stock option awards, as motive to falsely report positive results.[1] (¶¶ 14, 142-147.) However, during the period in which the price of Rigel's stock was allegedly inflated due to the fraudulent conduct of Defendants, none of the Defendants sold any of their stock in the Company.[2] (*See* Freeman Dec. ¶¶ 18-19, Exs. Q and R (Form 4s).) That is, none of them reaped the benefits of their alleged fraud. In fact, during that same period, each of the five officer Defendants increased their exercisable options and two acquired additional shares. (*See id.* ¶ 20.) Those five Defendants together lost $18.7 million[3] by retaining their shares leading up to the 2008 ACR conference when they allegedly knew that "the truth would come out." Allegations that Defendants earned salaries for their work add nothing to an inference of scienter.

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[1] Plaintiff cites *In re Cornerstone Propane Partners, L.P. Sec. Litig.*, 355 F Supp. 2d 1069 (N.D. Cal. 2005), and *Zucco* in support of its argument that Rigel's compensation structure served as a motive for the alleged fraud. In both cases, however, the courts dismissed the actions due to, among other things, a failure to adequately allege scienter despite the alleged link between the companies' compensation structure and the alleged frauds. *Cornerstone*, 355 F. Supp. at 1092 (plaintiff's allegations regarding defendants' incentives were "legally and factually insufficient" to support a strong inference of scienter); *Zucco*, 552 F.3d at 1005 (plaintiff's "bare assertion that executive-level bonuses were 'based in part' on [the company's] financial performance" were "inadequate to meet the heightened pleading requirements of *Silicon Graphics* and *Tellabs*").

[2] Seemingly unperturbed by the total *absence* of stock sales by individual Defendants, Plaintiff brazenly asserts that the *lack* of sales actually "adds to the inference of scienter" (Opp. at 23, n.25), because Defendants did not want to raise flags for potential partners. (Opp. at 24:1-6). This non-sequitur proves only that Plaintiff and its attorney can craft imaginative arguments; it hardly contributes to a compelling inference of intent to deceive.

[3] According to the Complaint, the price of Rigel stock fell $5.57 on October 28, 2008, and $.67 on February 3, 2009, as a result of the alleged fraud being disclosed. (¶¶ 18, 20.) According to SEC filings, the five officer Defendants owned roughly 3 million shares outright or through options during that time period. (*See* Freeman Dec. ¶ 20.)

In the absence of actual facts to suggest scienter, Plaintiff advances the unorthodox claim that the individuals are derivatively responsible for a form of "insider trading" by reason of Rigel's secondary offering. This claim is unsupported as a matter of law. Ample authority supports the conclusion that a company's plan to raise capital simply does not give rise to an inference of scienter. *See e.g., Lipton v. Pathogenesis Corp.*, 284 F.3d 1027, 1035-1038 (9th Cir. 2002) (allegations that defendants were motivated to impress lenders to secure funding, that defendants received reports indicating flat sales but made public statements to the contrary, and that the CEO sold company stock during the purported class period were insufficient to allege fraud); *In re Axonyx Sec. Litig.*, 2009 WL 812244, at *4 (S.D.N.Y. March 27, 2009) (allegations that defendant "used the announcement of the clinical trial to entice investors to participate in the company's private placements" were insufficient to plead scienter where there was no "hidden agenda" and the company was forthright in its goal to secure operating capital); *Ree v. Pinckert*, No. C99-0562 MMC, slip op. at 17 (N.D. Cal. Mar. 28, 2000) (rejecting secondary stock offering as basis to establish scienter) (attached as Ex. T to Supplemental Declaration of William S. Freeman ("Supplemental Freeman Dec.")).

The cases cited by Plaintiff come nowhere close to supporting its proposition that the 2008 secondary offering gives rise to an inference of scienter. *McCormick v. The Fund Am. Cos., Inc.*, 26 F.3d 869 (9th Cir. 1994), dealt, on summary judgment, with the question of whether the minority shareholder plaintiff was entitled to additional disclosures by the corporation before entering into a stock buy-back agreement. The court found that the information withheld was not material and did not support an inference of scienter. *Id.* at 884 n.8. Plaintiff's quote from *Shaw v. Digital Equip. Corp.*, 82 F.3d 1194 (1st Cir. 1996), is an explanation of the rationale behind liability under Section 11, and has nothing to do with scienter or claims under Section 10(b).[4] Plaintiff also inexplicably relies on *In re Cadence Design Sys.*, 2010 WL 726515 (N.D. Cal. Mar.

[4] Moreover, *Shaw* was superseded in part by the PSLRA. *Shaw* stated that the factual allegations must provide a basis for a reasonable inference of scienter. Under the PSLRA, a plaintiff must plead facts that give rise to a strong inference of scienter to survive a motion to dismiss. A mere reasonable inference is insufficient to survive a motion to dismiss. *See Greebel v. FTP Software, Inc.*, 194 F.3d 185, 196-97 (1st Cir. 1999) (noting "reasonable inference" language was used in pre-Act case law including *Shaw*).

2, 2010), which did not involve any secondary offering or sale of stock and, thus, provides no relevant guidance.[5]

Finally, as a matter of common sense, it cannot be the case that a company's stock offering can, even indirectly, serve as evidence of scienter under Section 10(b). Otherwise, every alleged Section 11 violation could be shoehorned into a Section 10(b) claim such that the allegation of specific facts demonstrating intent would be all but unnecessary. Such a conclusion is contrary to the weight of authority. *See In re Portal Software, Inc. Sec. Litig.*, 2005 WL 1910923, at *12 (N.D. Cal. Aug. 10, 2005) (finding no strong inference of scienter where defendants raised $60 million in a secondary offering two months before alleged corrective disclosure even where such financing was necessary to keep company a going concern); *In re Metricom Sec. Litig.*, 2004 WL 966291, at *35 (N.D. Cal. Apr. 29, 2004) (finding no strong inference of scienter where plaintiffs alleged that defendants engaged in public offering in order to raise "huge amounts of additional capital" even where defendant company filed for bankruptcy less than 18 months after public offering).

When viewed in light of all of the undisputed facts, the far more compelling inference is that Defendants acted in good faith, without an intent to deceive. Rigel's voluntary disclosure of detailed patient data to a scientific audience, in advance of having secured a partnership agreement with a third party, is consistent with a pure, non-corrupt motive. Further, while Plaintiff alleges that bonuses and salary increases may have created a motive to engage in a fraud, the facts show that Defendants suffered a far larger financial loss by holding onto their existing shares and increasing their financial exposure to the Company. (*See* Freeman Dec. ¶¶ 18-20.) Defendants' acts negate an inference of scienter. *See Ronconi v. Larkin*, 253 F.3d 423, 435 (9th

[5] Plaintiff contends that the "February offering hampered defendants [sic] ability to sell stock during a large chunk of the Class Period." (Opp. at 23 n.25.) Plaintiff is wrong. In fact, Plaintiff fails to make a single allegation regarding the lock-up provision in its CAC. The reason is clear: the alleged class period begins on December 13, 2007 and ends on February 3, 2009 (¶ 1), lasting a total of 419 days. As part of the February 2008 offering, Defendants were only bound by a 45-day lock-up period. (*See* Supplemental Freeman Dec. Ex. U (Form 424B3) at 30.) Forty-five days is hardly a "large chunk" of the class period.

Cir. 2001) (when corporate insiders collectively fail to seize a prime opportunity to "gain[] market advantage from as yet undisclosed bad news," an inference of scienter is negated).

III. THE COMPLAINT FAILS TO ADEQUATELY ALLEGE FALSITY

A. Plaintiff Fails to Adequately Allege That the Company's Statements Regarding Its Partnership Prospects Were False

Plaintiff alleges that Defendants' statement in October 2008 that Rigel was "on track" for a partnership was false when made (Opp. at 3:14-16), and that Rigel was not "on track" for a partnership because "before making a $100+ million commitment to develop R788 any potential partner would have been informed by due diligence (i.e. the actual results) that R788 had not demonstrated the efficacy that would support such a commitment." (*Id.* at 3:16-19.)

Not surprisingly, Plaintiff has not alleged a single fact showing that the statement that Defendants were "on track" for partnership was false when made in October 2008, or that Defendants knew it was false. Plaintiff fails to cite a single internal communication from that time period suggesting that the Company's efforts had derailed, a single document showing that the Defendants did not believe they were on track when they made that statement, or a single witness to support its allegations. Nor can Plaintiff credibly allege that the information actually disclosed by Rigel showed that "R788 had not demonstrated the efficacy that would support a [$100+ million] commitment." The fact that AstraZeneca made just such a commitment after Rigel's detailed scientific presentations supports that the drug *had* demonstrated sufficient efficacy to support such a commitment.

Moreover, Plaintiff incorrectly claims Rigel's statement about "putting the partnership in place as early as the early part of next year" concerned a current business condition and was, therefore, not protected by the PSLRA's safe harbor provisions. (Opp. at 13 n.15.) As Judge Walker has explained, the definition of forward-looking statements includes: "statements containing projections of revenues, income, earnings per share, management's plans or objectives for future operations and predictions of future economic performance." *In re Copper Mountain Sec. Litig.*, 311 F. Supp. 2d 857, 880 (N.D. Cal. 2004) (*citing* 15 USC § 78u-5(i)(1)(A)-(C)). A present-tense statement is forward-looking "'if the truth or falsity of the statement cannot be

discerned until some point in time after the statement is made.'" *Id.* (*quoting In re Splash Tech. Holdings, Inc. Sec. Litig.*, 2000 U.S. Dist. LEXIS 15369, *17 (N.D. Cal. Sept. 29, 2000) and *citing Harris v. Ivax Corp.*, 182 F.3d 799, 805 (11th Cir. 1999)). Clearly, a statement regarding when and whether Rigel would enter into a partnership was a projection that could only be verified in the future. It was, therefore, protected by the PSLRA's safe harbor provisions. Further, even if the statement was not protected by the safe-harbor provisions, an optimistic prediction of a future partnership is not actionable. *See Yourish v. Cal. Amplifier*, 191 F.3d 983, 997 (9th Cir. 1999); *Ronconi*, 253 F.3d at 430 (optimistic prediction about a merger that did not come to pass "does not raise a strong inference that defendants actually knew their forward looking statements to investors were false or misleading when made").

B. Nothing in the Opposition Changes the Fact that Plaintiff's Efficacy Claims Boil Down to Disagreements Regarding the Trial's Design and Interpretation

1. Plaintiff's Attempt to Disguise Conclusions As "Facts" Fails

While the Court must accept Plaintiff's well-pleaded facts as true on a motion to dismiss, it need not adopt Plaintiff's conclusory allegations. *In re Stac Elecs. Sec. Litig.*, 89 F.3d 1399, 1403 (9th Cir. 1996). Moreover, the Court is not required to accept as true unwarranted deductions, unreasonable inferences, or allegations that contradict materials properly subject to judicial notice. *See Clegg v. Cult Awareness Network*, 18 F.3d 752, 754-55 (9th Cir. 1994). Here, Plaintiff attempts to present conclusions and argument as fact. The opinion of Mr. Bloch, Plaintiff's retained consultant, that his is the only correct way to view and interpret clinical trial data is a conclusion, and it is not converted into a "fact" simply by quoting it in the CAC.

2. Plaintiff's Efficacy Claims Are Nothing More Than Non-Actionable Disputes Regarding Trial Design and Interpretation

In light of Defendants' demonstration that a Section 10(b) claim cannot be based on disagreements with the design of Rigel's clinical trial or Rigel's interpretation of the resulting data (MTD at 13-17), Plaintiff goes to great lengths to deny that this is indeed the basis of its claims. Plaintiff's denials, however, are based on distortions of its own CAC and of the views of its retained consultant.

First, Plaintiff argues that it has no problem with the design, methodology or interpretation of Rigel's study, but rather with the presentation of the results. (Opp. at 9:7-19.) This claim is demonstrably untrue. Plaintiff's assertion that there was "'no reasonable support in the data' for the glowing efficacy results defendants touted to the market" is based on the alleged unequal distribution of patients between the U.S. and Mexico and the unbalanced dose distribution among Mexican and American patients. (Opp. 8:23-24.) These are unquestionably quarrels with the study's design as the problems identified by Plaintiff only arise as a result of the way in which subjects were distributed among the clinical sites in the U.S. and Mexico and among different dosing groups.

The fact that Plaintiff seeks judicial notice of the FDA's Notice of "International Conference on Harmonisation; Guidance on Statistical Principles for Clinical Trials; Availability" ("FDA Notice") only confirms that Plaintiff's issue is with Rigel's trial design. The FDA Notice states that "[g]ood *design* should generally aim to achieve the same distribution of subjects to treatments within each center and good management should maintain this *design* objective." (Declaration of S. Asher Ahmed in Support of Plaintiff's Request for Judicial Notice ("Ahmed Dec."), Ex. 1 at 14) (emphasis added.) Indeed, Plaintiff even quotes directly from the section entitled "III. Trial Design Considerations." (Ahmed Dec. Ex. 1 at 12 & 14.)

Plaintiff's further statement that "FDA guidelines state that multi-site effects *must* be accounted for" (Opp. at 11:12-15 (emphasis added)) is flatly untrue. The FDA Notice states that "heterogeneity of treatment effect . . . implies that alternative estimates of the treatment effect, giving different weights to the centers, *may* be needed to substantiate the robustness of the estimates of treatment effects." (Ahmed Dec. Ex. 1 at 15) (emphasis added.) The FDA Notice's permissive guideline is hardly the mandatory requirement that Plaintiff makes it out to be. Moreover, the FDA Notice explicitly states that it "does not address the use of specific statistical procedures or methods." (Ahmed Dec. Ex. 1 at 6.) Notably, Plaintiff never claims Defendants incorrectly applied their chosen statistical method, or reached mathematically incorrect results.

Yet, Plaintiff contends that Defendants made false and misleading statements under the "basic tenets of statistics," (Opp. at 2:9), and based on understated p-values. (Opp. at 17-18.)

This is a dispute about which statistical methods Rigel should have used to interpret its trial data, which, under settled law discussed at length in Defendants' Opening Memorandum, cannot serve as a basis for securities fraud. *See Padnes v. Scios Nova Inc*., 1996 WL 539711, at *5 (N.D. Cal. Sept. 18, 1996); *DeMarco v. DepoTech Corp.*, 149 F. Supp. 2d 1212, 1225-26 (S.D. Cal. 2001); *In re Adolor Corp. Sec. Litig.*, 616 F. Supp. 2d 551, 568 n.15 (E.D. Pa. 2009) ("The fact that Variant's statistician reached a different conclusion [regarding statistical significance] does not establish that Adolor's interpretation of results were false or misleading.").

Plaintiff's allegation that there was "no reasonable support in the data" for Defendants' positive statements regarding R788's efficacy is meritless. Rigel's statistical analysis of its trial data was accepted for publication in the well-established peer-reviewed national journal *Arthritis & Rheumatism*. This alone supports Defendants' position that there was adequate support for Rigel's statistical methods. *Padnes*, 1996 WL 539711, at *6 (study's publication "in a peer-reviewed journal[] indicat[ed] that specialists in the field believed it had some scientific value").

Finally, with regard to the efficacy of the drug, Plaintiff wrongly claims that Rigel sought to create "[t]he impression of an ascending dose response" that "was not supported by the results," specifically pointing to the "belated" disclosure that the 150 mg dose worked no better than 100 mg. (Opp. at 10:12-15.) Defendants never made such a claim. In December 2007, Dr. Grossbard was clear that of the three doses of R788, "the 50 milligram dose [does] not appear to be much better than placebo" and "the efficacy results for the two effective doses (100 and 150 mg) were fairly comparable . . .." (Freeman Dec. Ex. E at 3.) Rigel accurately stated that there was *a* dose response in that 100 mg worked better than placebo or 50 mg, but did not state that there was an "ascending" response, reporting early on that there was no significant difference between 100 and 150 mg.

C. Plaintiff Fails to Adequately Allege Any Material Misrepresentation with Regard to Its Safety Claims as the Detailed Data Disclosed in 2008 Was Consistent with the Earlier Top Line Data Disclosed in 2007

1. Plaintiff Has Failed to Comply With the Court's Order Dismissing the Consolidated Complaint

Plaintiff appears to have abandoned its earlier claims that Defendants made false and misleading statements. Instead, Plaintiff argues in the Opposition that Defendants' truthful

statements somehow created a false "impression" about the trial results. (Opp. at 3:3, 10:12, 13:4.) Plaintiff has tried this tactic before. In its Order dismissing the Consolidated Complaint, the Court stated that "[t]o the extent Plaintiff intends to argue that statements which are not actually false or misleading, but contribute to a general false impression when considered with other statements, are actionable, Plaintiff should be prepared to provide authority in support of this proposition." (Order at 11 n.3.) Plaintiff has cited no new authorities in support of this argument, instead recycling the argument that "defendants' statements related to R788's safety results are to be viewed in context as a totality, not . . . in piecemeal fashion." (Opp. at 15:7-8.) Moreover, the cases cited by Plaintiff in support of this argument are the same cases cited in Plaintiff's opposition to Defendants' previous motion to dismiss, with which the Court was undoubtedly familiar. (*Compare* Opp. at 15:7-20 (filed 3/9/10) *with* Opp. at 20:6-18 (filed 10/23/09).)

Further, the cases Plaintiff cites are inapplicable. In fact, *Bourjaily* is not even a securities fraud case, but rather a criminal drug case dealing with the reliability of out-of-court statements by co-conspirators. *Bourjaily v. United States*, 483 U.S. 171, 179-180 (1987). The other two cases cited in support are similarly unavailing.[6]

2. Defendants' 2007 Disclosures Were Not Materially Misleading

Plaintiff continues to rely on mischaracterizations of the initial top-line disclosures in December 2007 to support its argument that the later, more detailed disclosures revealed material omissions in the earlier statements. Rigel never represented in December 2007 that it was

[6] Neither case supports the notion that several literally true statements can, when considered together, create a "false impression" sufficient to support a Section 10(b) claim. In *McMahon & Co. v. Wherehouse Entertainment, Inc.*, 900 F.2d 576, 579 (2d Cir. 1990), the court reversed summary judgment, finding that there could be a factual dispute as to whether defendants' representations about the rights of debenture holders under certain triggering events were illusory. The court held that a literally true statement could be part of a scheme to defraud if its significance was "obscured" or "distorted" by other statements made by the defendant. 900 F.2d at 579. In *In re Apollo Group, Inc. Sec. Litig.*, 395 F. Supp. 2d 906, 921 (D. Ariz. 2005), the court reviewed in detail six separate alleged misrepresentations concerning the existence and results of a Department of Education investigation, and concluded that "each of the defendants' representations discussed above . . . were [sic] false, deceptive and misleading." 395 F. Supp. 2d at 917.

disclosing *all* side effects; to the contrary, both the language of its initial press release (referring to "key safety results") and the chart contained in that release make it clear that Rigel was only discussing *moderate-to-severe* adverse events. No reasonable investor could have reviewed the press release or listened to the publicly-accessible conference call and concluded the Company had discussed *every side effect observed regardless of severity*. (Freeman Dec. Ex. D (12/13/07 Form 8-K, Ex. 99.1) at 2; Ex. E (12/13/07 trans.) at 3.)

Further, unlike the cases cited by Plaintiff, there are no allegations that Defendants failed to disclose key safety data. For example, *Twinde v. Threshold Pharmaceuticals, Inc.*, 2009 WL 928132, at *11 (N.D. Cal. Apr. 3, 2009) deals with the failure of a company to disclose severe incidents of liver toxicity that arose in its clinical trials. However, the safety concerns in that case were so severe that it led the FDA to place a partial hold on the clinical trials. *Id.* That is hardly the case here, where Defendants disclosed the most significant adverse events from the outset. *See also In re Connetics Corp. Sec. Litig.*, 2008 WL 3842938, at *1 (N.D. Cal. Aug. 14, 2008) (company failed to disclose results of a study showing that drug may cause cancer) (cited in Opp. at p. 15). Plaintiff fails to allege a single fact to support the claim that the explicit omission of information relating to the most mild side effects threatened the commercial viability of R788. The alleged omissions are therefore immaterial. *Masters v. GlaxoSmithKline*, 271 Fed. Appx. 46, *50 (2d Cir. Mar. 26, 2008) (unpublished decision) ("[R]eports of harmful drug effects are immaterial—and thus need not be disclosed—unless those reports (1) show statistically significant evidence of an adverse effect, (2) establish that the adverse effect directly threatens the 'commercial viability' of the drug; and (3) show the effect poses a significant risk to the company's future earnings.").[7]

[7] Plaintiff continues to maintain that Defendants misled investors when they disclosed key safety results related to diarrhea, GI side effects and hypertension of "severity moderate or greater" in December 2007 without explaining what these "terms of art" meant. (Opp. at 15:21-25.) These are not terms of art. A reasonable investor could read the disclosures and understand what was meant—that moderate and severe incidents of diarrhea, GI side effects and hypertension were being disclosed and mild incidents were not.

Defendants will not repeat all of the detailed arguments regarding the various safety claims set forth in our Opening Memorandum. (MTD at 17-22.) However, a few comments in response to the arguments in the Opposition brief related to blood pressure are in order.

On that front, Plaintiff's basic claim continues to be that the Company misled investors in 2007 by failing to disclose data regarding blood pressure risk. In doing so, Plaintiff continues to ignore the fact that the Company disclosed at that time that two patients had experienced moderate to severe hypertension while in the trial, a medical condition that often requires treatment. Thus, there is no question that the Company disclosed in 2007 that there was a blood pressure risk with the R788. Plaintiff simply complains that the Company should have disclosed more, without indicating in any way how that additional information would have been material. Plaintiff also continues to mischaracterize Dr. Grossbard's statements regarding blood pressure. Plaintiff's claim that Dr. Grossbard "conceded" that an increase in average blood pressure was "of crushing importance to everybody" is demonstrably false. (Opp. at 16:9-11.) An accurate reading of the October 27, 2008 transcript shows that Dr. Grossbard was responding to an entirely different question: whether patients who had their doses reduced did so *either three weeks or five weeks* into the study period. (Freeman Dec. Ex. I (10/27/08 trans.) at 8-9.) Moreover, Dr. Grossbard's statements in October 2008 regarding the plan to further research R788's impact on blood pressure was not new information as Plaintiff contends. (¶ 99; Opp. at 16:11-12.) Dr. Grossbard stated on December 13, 2007 that the drug's safety profile was "going to be a close focus of the future program." (Freeman Dec. Ex. E (12/13/07 trans.) at 3.)

In support of its argument that the market reacted to the allegedly "shocking" nature of the information disclosed in October 2008, Plaintiff selectively quotes from analyst reports. (Opp. at 16:13-17:7.) For example, while Plaintiff quotes Credit Suisse analyst Aberman's statements that "blood pressure was 'probably the biggest risk to the program' and 'could precipitate significant morbidity acutely'" (Opp. at 16:17-19), Plaintiff ignores the rest of Aberman's report, which repeatedly states that "new data [did] not dramatically change our view." (Freeman Dec. Ex. J

(10/27/08 Credit Suisse, cited at ¶¶ 73, 104, 173) at 1) ("[T]he company has talked about the effect on [blood pressure] since the data was first presented.").[8]

IV. PLAINTIFF'S SECTION 11 CLAIMS SHOULD BE DISMISSED

Regardless of whether fraud is a necessary element of a claim, where a plaintiff chooses to allege that defendants engaged in a uniform course of fraudulent conduct, that plaintiff's claims are "grounded in fraud" and must satisfy Rule 9(b)'s particularity requirement. *Vess v. Ciba-Geigy Corp.*, 317 F.3d 1097, 1103-04 (9th Cir. 2004); *Kearns v. Ford Motor Co.*, 567 F.3d 1120, 1125 (9th Cir. 2009). There is no doubt that Plaintiff's claims in this case are grounded in fraud; all one need do is to look at the argument headings in the Opposition to confirm that Plaintiff alleges a course of knowing conduct.[9] Plaintiff's contention that because the "CAC not only specifically ***disclaims*** allegations of fraud with respect to the 1933 Act" but "incorporates ***only*** the non-fraudulent allegations into those claims" changes nothing. (Opp. at 6:13-15 (emphasis in the original).) *See In re Mikohn Gaming Corp. Sec. Litig.*, 2006 WL 2547095, at *9-*10 (D. Nev. Sept. 1, 2006) (holding Securities Act claims and Exchange Act claims must both be pled with particularity under Rule 9(b) since claims relied upon same course of fraudulent conduct, despite statement in complaint that "Securities Act claims do not incorporate by reference or otherwise rely on the fraud based allegations" of the Exchange Act claims); *In re Metropolitan Sec. Litig.*,

[8] Further, the market was aware in December 2007 that mild levels of hypertension were a possibility with R788. (*See, e.g.*, Freeman Dec. Ex. F (12/13/07 CIBC World Markets, cited at ¶¶ 63, 66, 118) at 4 ("Rigel did not report the rates of mild hypertension in this study. However, even if mild hypertension were to be observed, we believe this would likely be acceptable in the moderate-to-severe RA setting, given that hypertension also appears to occur at a slightly higher rate among patients on biologic therapy.").) Several analysts, in reports referenced in the CAC, commented that nothing in Rigel's October 2008 statements was new or surprising. (*See, e.g.*, Supplemental Freeman Dec. Ex. V (11/3/08 Credit Suisse, cited at ¶¶ 105, 175) at 2 ("[W]e were aware of that [blood pressure] risk prior to ACR through the 5% incidence of hypertension disclosed in the original Phase IIa top-line data disclosure."); Ex. W (10/28/08 SIG, cited at ¶¶ 19, 136, 173) at 1 ("[H]ypertension is not a new concern as it was seen in the ITP and lymphoma studies . . .."); Ex. X (11/4/08 Jefferies, cited at ¶ 140) at 1 ("We believe R788 previously described (Dec 07) ability to marginally increase blood pressure (4-5 mmHg) should . . . not have come as a surprise to the Street and consultants view it as an easily treated side effect.").)

[9] *E.g.*, "Defendants Knowingly Made Materially False and Misleading Statements About the Efficacy Results of R788"; "Defendants Knowingly Reported Materially Misleading Safety Results and Concealed Material Adverse Safety Information"; "Defendants Had Actual Knowledge of the Falsity of Their Statements." (Opp. at 8, 12, 19.)

532 F. Supp. 2d 1260, 1278-79 (E.D. Wa. 2007) (finding Section 11 claims must be pled with particularity because "[a]part from their references to Defendants' states of mind, the [complaint's] fraud and [Section 11] counts are virtually identical" despite plaintiffs' argument that complaint alleges facts in support of fraud claims that do not go to Section 11 claims). Plaintiff's "nominal disclaimers" are "unconvincing where the gravamen of the complaint is plainly fraud and no effort is made to show any other basis for the claims . . . ." *In re Stac Elecs. Sec. Litig.*, 89 F.3d 1399, 1405 n.2 (9th Cir. 1996). Plaintiff's allegations regarding Defendants' conduct are wholly inconsistent with a negligence theory. Indeed, all of the allegedly misleading statements in the registration statement are statements Plaintiff alleges were knowingly false when made. Plaintiff also affirmatively links its Section 11 claims to its Rule 10b-5 claims by alleging that Rigel's secondary offering is evidence of scienter (Opp. at 21-23) further undermining its argument.[10] Thus, in addition to failing to allege that Defendants made a false or misleading statement, Plaintiff's Section 11 claims should also be dismissed for failing to comply with Rule 9(b)'s particularity requirement.

V. CONCLUSION

For all of the foregoing reasons, Defendants respectfully request that the Court grant Defendants' motion to dismiss Plaintiff's Consolidated Amended Complaint with prejudice.

Dated: March 18, 2010

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[10] When citing *In re Intrabiotics Securities Litigation*, (Opp. at 6:3-5), Plaintiff conveniently ignores this Court's later decision in the case in which the Court reversed its earlier finding that plaintiff's Section 11 claims were not "grounded in fraud" and held that plaintiff was required to plead its Section 11 claims with particularity under Rule 9(b). 2006 WL 2192109, at *16 (N.D. Cal. Aug. 1, 2006).